EXHIBIT 10

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	: MDL NO. 2875 : : : VIDEOTAPED DEPOSITION : UPON : ORAL EXAMINATION : OF : RAMIN (RON) NAJAFI, X Ph.D., VOLUME II

TRANSCRIPT of the stenographic notes of the proceedings in the above-entitled matter, as taken by and before ELLEN J. GODINO, CCR, RPR, CRCR, held via ZOOM VIDEOCONFERENCE from various locations, with the witness located at 1000 Atlantic Avenue, Suite 110, Alameda, California, on Wednesday, January 24, 2023, commencing at 8:10 a.m. Pacific Time.

A P P E A R A N C E S:
FOR PLAINTIFFS:

MAZIE SLATER KATZ & FREEMAN
BY: CHRISTOPHER J. GEDDIS, ESQ.
103 Eisenhower Parkway
2nd Floor
Roseland, New Jersey 07068
973-228-9898
cgeddis@mazieslater.com

LEVIN PAPANTONIO RAFFERTY
BY: DANIEL NIGH, ESQ.
316 South Baylen Street
Pensacola, Florida 32502
850-435-7013
dnigh@levinlaw.com

FOR ZHEJIANG HUAHAI PHARMACEUTICAL, CO., LTD.:
SKADDEN ARPS SLATE MEAGHER & FLOM, LLP
BY: NINA R. ROSE, ESQ.
ALEXANDER J. KASPARIE, ESQ.
One Manhattan West
New York, New York 10001-8602
212-735-3000
nina.rose@skadden.com
alexander.kasparie@skadden.com

FOR TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., ACTAVIS PHARMA, INC., AND ACTAVIS LLC:

GREENBERG TRAURIG, LLP
BY: STEVEN M. HARKINS, ESQ.
Terminus 200
3333 Piedmont Road NE, Suite 2500
Atlanta, Georgia 30305
678-553-2100
harkinss@gtlaw.com

A P P E A R A N C E S (Continued):
MARTIN, HARDING & MAZZOTTI, LLP
BY: ROSEMARIE RIDDELL BOGDAN, ESQ.
P.O. Box 15141
23 Albany, New York 12212
518-724-2207
Rosemarie.bogdan@1800law1010.com

FOR PFIZER INC., VALEANT PHARMACEUTICALS INTERNATIONAL, INC., BAUSCH & LOMB INCORPORATED, AND ATON PHARMA, INC.:
WALSH PIZZI O'REILLY FALANGA, LLP
BY: CHRISTINE I. GANNON, ESQ.
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102
973-757-1100
cgannon@walsh.com

FOR MYLAN PHARMACEUTICALS INC., AND MYLAN LABORATORIES, LTD.:
PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP
BY: FRANK. H. STOY, ESQ.
One Oxford Centre
301 Grant Street, 38th Floor
Pittsburgh, Pennsylvania 15219
412-263-4397
fhs@pietragallo.com

FOR TORRENT PHARMA INC. & TORRENT PHARMACEUTICALS, LTD.:
KIRKLAND & ELLIS, LLP
BY: BRITTNEY NAGLE, ESQ.
601 Lexington Avenue
New York, New York 10022
212-390-4210
brittney.nagle@kirkland.com

A P P E A R A N C E S (Continued):
FOR HETERO LABS, LTD:
HILL WALLACK, LLP
BY: WILLIAM P. MURTHA, JR., ESQ.
777 Township Line Road
Suite 250
Yardley, Pennsylvania 19067
267-759-2064
wmurtha@hillwallack.com
LEVIN PAPANTONIO RAFFERTY
BY: DANIEL NIGH, ESQ.
316 South Baylen Street
Pensacola, Florida 32502
850-435-7013
dnigh@levinlaw.com

FOR DEFENDANT SCIEGEN PHARMACEUTICALS, INC:

HINSHAW & CULBERTSON, LLP
BY: GEOFFREY M. COAN, ESQ.
53 State Street
Boston, Massachusetts 02109
617-213-7045
617-213-7001
gcoan@hinshawlaw.com

ALSO PRESENT:
BEN PELTA-HELLER, Videographer

I N D E X

EXHIBITS

E X H I B I T S (Continued)

Number	Description	Page
Najafi-18	FDA Document entitled "Guidance for Industry, Q3A Impurities in New Drug Substances," Revision 2 dated June 2008, No Bates, 17 Pages	333
Najafi-19	FDA Document entitled "Guidance for Industry, Q3B(R2) Impurities in New Drug Products," Revision 3, August 2006, No Bates, 18 Pages	340

THE VIDEOGRAPHER: Good morning. We are going on the record at 8:10 a.m. on Tuesday, January 24, 2023. This begins Media Unit 1 of the video-recorded deposition of Dr. Ron Najafi, Volume II, taken by counsel in the matter of In Re: Valsartan.

My name is Ben Pelta-Heller, representing Veritext, and I'm the videographer. The court reporter is Ellen Godino, from the firm Veritext.

All counsel will be noted on the stenographic record, and will the reporter please swear in the witness.

R A M I N (R O N) N A J A F I, Ph.D., having been duly sworn, testified as follows:

EXAMINATION BY MS. ROSE:

Q. Hi, Dr. Najafi. Good to see you again.

A. It's good to see you, too.

Q. Today we are continuing the deposition that began on January 18, 2023. Correct?

A. That is correct.

Q. And because it's a new day, I'm going to reconfirm a few things we went over with the first deposition.

Aside from Zoom, do you have any other

software open on your computer?

A. No, I don't.

Q. You don't have any mail or messaging software open?

A. (No audible response.)

Q. I'm sorry, I didn't hear that.

A. No, I don't.

Q. Will you agree not to email, message or have any other private communications with anyone while we are on the record?

A. Yes, I do.

Q. Will you agree not to open any documents on your computer, other than the ones you may be shown on the Veritext platform?

A. Yes, I will.

Q. Have you had any alcoholic drinks in the past eight hours?

A. No, I have not.

Q. Are you on any medication that would prevent you from providing accurate testimony?

A. No, I do not.

Q. Is there any other reason you cannot give complete and accurate testimony today?

A. No.

Q. Since the last session of your

deposition, have you spoken with the plaintiffs' lawyers in this case?

A. Yes, I have.

Q. How many times?

A. I would say a couple times.

Q. And for how long did you speak on each of those two times that you spoke?

A. Ten, 15 minutes.

Q. Ten, 15 minutes each?

A. (No audible response.)

(Court Stenographer clarification.)

A. Yes.

Q. Thank you. Did you review any documents since the last session of your deposition, related to this case?

A. Yes, I have.

Q. Which documents?

A. I've reviewed my expert report, and I've also reviewed the Loeppky document.

Q. And since the last session of your deposition, have you found any other new documents that you claim support your opinions, that you have not previously disclosed?

A. No.

Q. Dr. Najafi, at the first session of your

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deposition, you told me that you had mistakenly failed to include in your report, or list in Materials Considered, certain scientific articles that you believe support some of your opinions. Correct?

MR. NIGH: Form objection.

A. That's correct.

Q. And as I recall, we were specifically talking about page 27 to 28 of your report, which was marked as Exhibit 7.

MS. ROSE: Can we bring that up?

THE VIDEOGRAPHER: I'm sorry, what page number?

MS. ROSE: It's Exhibit 7.

Okay. And we're going to page 27 at the bottom. Perfect.

Q. There at the very bottom, about four lines up, we were talking about your statement that during the quenching of sodium azide with sodium nitrite during both the TEA and zinc chloride processes, there was -- and I'm going to quote here -- "a substantial risk during this step that nitrous acid is formed, which can nitrosate trimethylamine, dimethylamine, and form NDMA, as well as nitrosate triethylamine or diethylamine to form

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NDEA. This is a well-established textbook reaction that should be recognized by process chemists working in the pharmaceutical industry companies" -- sorry -- "pharmaceutical industry for companies like ZHP."

Correct?

MR. NIGH: Form objection.

A. Would you highlight the section that you're referring to, because I don't -- I don't see it on the screen?

Q. Sure.

MS. ROSE: Dan -- right there. I'm sorry, Ben. Thanks.

A. Okay. Let me just -- give me a sec. I'm looking at the exhibit in the bigger text to -- if you'd be kind enough to give me a second so I can refresh my memory.

That's correct.

Q. Okay. At the time, you agreed that the document you cited for that proposition, which is on the next page --

MS. ROSE: We can move to 28. Thank you.

Q. Which is a page of a website about sodium azide, did not support the whole passage. Correct?

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MR. NIGH: Form objection.

A. That is correct.

Q. [Audio dropout] article by Sun. Is that correct?

(Court Reporter Clarification.)

MS. ROSE: Oh, I'm sorry.

I said, after taking a break, plaintiffs' counsel provided me with three documents that Dr. Najafi claims supported the proposition we just read in his report. And the first one was a link to a 2010 article by Sun that just included the abstract.

Q. Do you recall that, Dr. Najafi?

MR. NIGH: Form objection.

A. Yes, I do.

MS. ROSE: Can we put up Tab 57.

Q. Dr. Najafi, is this the abstract that your counsel provided to me during the first session of your deposition?

MR. NIGH: I actually haven't seen it come in the documents yet.

MS. ROSE: Oh, okay.

A. I cannot see it. You know, if you could -- is it on the exhibit portion?

MR. NIGH: It's not there yet.

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Q. It's right up on the Zoom screen. It also should be up on the exhibit portion.

A. Exhibit what?

Q. Oh, sorry, apologies. It should be Exhibit 15. I'll mark it as that.

A. 15. I don't -- I don't have it yet.

MR. NIGH: Dan, have you put it in the folder? There it is, I see it now.

Just refresh it again, Dr. Najafi.

THE WITNESS: Okay.

A. Okay, I got it. Give me a sec. This is -- the title is, "Theoretical Investigation of N-Nitrosodimethylamine Formation From Nitrosation of Trimethylamine."

Q. Correct.

A. Correct. So I'm -- yeah, yes. That is -- that is one of the articles. Let me take a look at the pathway they're showing here.

So I am -- I meant not to cite this article, per se. Loeppky is the one that I would have cited since that was in my possession at that time.

This is an article that, you know, my -- our lawyers pointed out to me. But it also supports my, you know, assertion that trimethylamine,

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triethylamine, tripropylamine, basically any trialkyl amine, can get nitrosated with nitrosonium ions, and undergo the pathway that Sun and -- you know, the authors, Sun, et al., are pointing to.

Q. Okay. But you did not read this Sun article prior to forming your opinions in this case?

A. No.

Q. In addition --

A. However -- let me continue. However, this article further substantiates Loeppky, which is the one that I'm relying on.

Q. Okay. In addition to this online abstract for the 2010 Sun article, plaintiffs' counsel also provided me, during your first deposition -- sorry -- first session of this deposition, with a PDF of an article that was marked as having been used at the deposition of Peng Dong.

Do you recall that?

A. I believe I do. I have not reviewed that, you know, between our last conversation and today.

Q. Well, I'll represent that you told me at the first session of your deposition that the plaintiffs' counsel sent this to you -- sorry, sent that article that was used in the Peng Dong

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deposition; they sent that to you during a break in your deposition.

Do you recall that?

MR. NIGH: Form objection.

A. Yes.

Q. And had you seen --

A. Yes, I do.

Q. Okay, great. Had you seen that article that was marked as being used at the Peng Dong deposition prior to forming your opinions in this case?

A. I had.

Q. All right.

MS. ROSE: Let's put up Tab 56.

I don't think this is it. Sorry, that's my mistake. 58. Here we go.

A. This is exhibit number?

Q. Oh, sorry, this will be Exhibit Number 16. It should show up --

A. I don't have it.

Q. I think Ben is working on putting this into your Exhibit Share.

(Exhibit Najafi-16, Article entitled "Theoretical Investigation of N-nitrosodimethylamine Formation from Nitrosation of Trimethylamine," by Zhi

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Sun et al. from The Journal of Physical Chemistry, previously marked ZHP-211, was received and marked for identification.)

A. Okay.

Q. Do you see it now?

A. No. Oh, yes, I do.

Q. Okay. Great.

A. Yeah.

Q. Do you see that the title is "Theoretical Investigation of N-Nitrosodimethylamine From Nitrosation of Trimethylamine"?

A. That's the -- that's the Sun article, yes.

Q. Yeah. So would you agree that this is the full article for the last exhibit I just showed you, which was the online abstract for the same article?

A. Give me a second. I would have to confirm that by looking at the -- the Exhibit 15, just to make sure it is the same.

Q. Well, why don't we go off the record just for a second, and you can look at these two and just confirm whether they're the same?

MR. NIGH: No, that's not an appropriate reason to go off the record.

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MS. ROSE: I --

MR. NIGH: I'm sorry. That's not --

MS. ROSE: The Court has said that if he's reviewing documents, that we can go off the record.

MR. NIGH: That's incorrect. That's not what the Court said. It was a whole conversation about how much time they need to review a document; not to compare two documents to see if they're the same document.

MS. ROSE: All right.

BY MS. ROSE:

Q. Dr. Najafi, I will give you a minute or so to look through. One is a one-page document --

A. Okay.

Q. -- and it's identical titles and identical dates.

A. All right. So let me just double-check that. "Theoretical investigation of N-nitroso formation of dimethylamine" and -- they -- they seem to be --

(Cell phone ringing.)

A. Oh, sorry. It's not my doctor, sorry. It's not that.

They seem to be the right articles.

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They, you know, this should be that -- Exhibit 16 is -- looks -- seems like the full article for the abstract you've previously showed me.

Q. Okay. And you just testified, when we looked at the abstract for this article, that you had found it for the first time during your last session of your deposition. Correct?

MR. NIGH: Form objection.

A. I have reviewed hundreds of articles. I might have reviewed this as well, but I don't believe I've cited this article in my report.

Q. Okay. But the full Sun article, which you said that you had read prior to providing your report in this case, did you read that full article before forming your opinions, and are you relying on it for your opinions?

MR. NIGH: Form objection, asked and answered.

A. I have not read the full article. I scanned through it, and I -- I'm not relying on this article for my opinion.

Q. Okay. All right. Well, let's move on to the Loeppky article which you mentioned. So that --

A. Loeppky.

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Q. Oh, I'm sorry, Loeppky. Thank you for correcting my pronunciation.

So the Loeppky article that your counsel provided to me during the first session of your deposition, that is the only new article that you are relying on for the statements set forth in your report. Correct?

A. That is correct. However, my assertion that trialkyl amine converts to, effectively, dialkyl nitrosamine has also been substantiated by European Medical Authority, and I think that's another, you know, report that I've cited in my -- in my expert report.

Q. Sure. But I'm just asking, I'm trying to clarify. Because three documents were provided to me in the last session of deposition as new materials that you claim to have reviewed and meant to cite in your deposition.

But just for clarification: The only article that you reviewed prior to writing your report, and meant to cite in your report but did not, was this Loeppky article that your counsel provided to me in the last session. Correct?

MR. NIGH: Form objection.

A. Yes, that's correct.

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Q. Okay.

MS. ROSE: Okay. Let's pull up the Loeppky article. That's going to be Tab 59, and that will be exhibit -- I'm going to say 17?

MR. NIGH: Anita, did you want the full article? That's at Tab 60.

MS. ROSE: Oh, I apologize. Yes, let's do Tab 60.

(Exhibit Najafi-17, Article entitled "Ester-Mediated Nitrosamine Formation from Nitrite and Secondary or Tertiary Amines," by R.N. Loeppky et al., from IARC Scientific Publications, No Bates, 11 Pages, was received and marked for identification.)

Q. Okay. So this is a 1984 article entitled "Ester-Mediated Nitrosamine Formation from Nitrite and Secondary or Tertiary Amines," by Loeppky. Is that correct?

A. That's correct.

Q. And it's your testimony that you had this article in your possession, and read it and relied on it prior to drafting your report. Correct?

A. Yes, I have.

Q. Dr. Najafi, did ZHP's zinc chloride or TEA with quenching manufacturing processes --

(Court Reporter Clarification.)

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MS. ROSE: Oh, no problem. I'm not reading, just so you know. I'm just a fast talker.

Q. Did ZHP's zinc chloride or TEA with quenching manufacturing processes involve the use of ethylene glycol as a solvent?

A. Let me review the, you know -- that process. It's in my expert report.

Q. Oh?

A. Just give me a second.

Q. If you want to look at page 25 of your report, which was Exhibit 7.

A. Yes, I am looking at it as we speak. Okay. What is -- and what is your question?

Q. I was asking if ZHP's zinc chloride or TEA with quenching manufacturing processes involved the use of ethylene glycol as a solvent?

A. No, it does not use ethylene glycol. But your -- you know, you make your conclusion based on the fact that a trialkyl amine transforms to dialkyl amine, and then it gets nitrosated. And, you know, one, you know, often hypothesizes how a chemical gets transformed, often after the fact, where you see an impurity like NDEA, and then you try to develop a hypothesis and root cause analysis.

So that has been the conclusion of

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European Medical Authority, ma'am; and it's also the conclusion of Loeppky, based on my review of Loeppky and others, that trialkyl converts to dialkyl, and then gets nitrosated.

To -- you know, to assert that ethylene glycol is not present, I can tell you that there are other ester moieties are present within the ZHP's manufacturing process. And, you know, and that could simply catalyze the process.

Q. Okay. So if --

MR. NIGH: And I object to form of the question.

MS. ROSE: Okay.

Q. I believe the answer at the beginning of that was no, that ethylene glycol is not involved in the manufacturing processes used by ZHP.

You also mentioned an ester. Did ZHP's zinc chloride or TEA with quenching processes involve the use of the ester 2-acetoxyethanol?

MR. NIGH: Form objection.

A. Esters are present in the process of the ZHP transformation. The molecule of valsartan contains that ester.

Q. Which ester specifically?

A. I would, you know, basically -- do you

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see the -- right above "Purification Step"? Right above the purification step? I don't know if I can point to it.

(Simultaneous speaking.)

Q. Okay.

A. But you have COO -- COO methyl. COOCH3 is an ester.

Q. And is that ester 2-acetoxyethanol?

A. It does not have to be. You know, you make -- you make your hypothesis based on the fact that, A, you have this triethylamine impurity; or you have this tri -- you know, essentially, diethylamine -- nitrosodimethyl -- diethylamine present. And then you look back and see you have triethylamine; it's a logical conclusion.

So that's my expert opinion, and it's also the expert opinion of the authors of European Medical Authority document, as well as the Loeppky and others.

Q. Okay. But my specific question was: You just said COOCH3 was an ester. I'm just asking: Is that 2-acetoxyl -- sorry -- 2-acetoxylethanol? That's the only question I'm asking, because I don't know, I'm not a chemist.

A. No. No, it is not.

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Q. Okay. And is COOCH3 that you're identifying, is that -- would that be defined as a high-boiling ester?

A. You have -- yeah, it is a high-boiling ester.

Q. Does it depend on the temperature at which it is used, whether it's a high-boiling ester?

MR. NIGH: Form objection.

A. Something is a high-boiling ester, depends on its molecular weight.

Q. Okay. Did the zinc chloride or TEA processes involve the use of a nitrous ester?

A. No, they do not.

Q. Okay. If you look at page 2 of the PDF, which is the fourth full sentence --

MS. ROSE: Sorry, we're going back to Tab 60, which was, I believe, Exhibit 17.

Okay. So we're on page 2 of the PDF, fourth full sentence.

A. This is Exhibit -- Exhibit --

Q. It's the last exhibit, which I think is 17.

A. Got it. 17.

MR. NIGH: It shows up as Tab 60, on the document.

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Q. Tab 60.

MR. NIGH: Yeah.

A. Okay.

Q. It says, "In the course of verifying this hypothesis, we have investigated that reaction of secondary amines with the acetate esters of ethylene glycol, and sodium nitrite and ethylene glycol. These experiments have been performed to answer the question: Can esters and ionic nitrite lead to extensive nitrosation of secondary and tertiary amines? The results presented in this paper demonstrate that the answer is yes. Moreover, we believe that this general reaction scheme is mainly responsible for the production of N-nitrosamines in cosmetics, metal-working fluids, shampoos and other toiletry articles, as well as certain cooked and cured meats." Correct?

A. I am reading that statement.

Okay. And what is your question regarding this statement?

Q. This statement states that the point of the article is to evaluate the role of esters and ionic nitrite in the formation of nitrosamines. Correct?

MR. NIGH: Form objection.

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A. Yes, it -- it confirms that triethylamine or trimethylamine in the presence of sodium nitrite and ethylene glycol, or their corresponding ethylene glycol esters, could transform into, you know, nitrosamines.
Q. Do you know if any of the experiments described in these papers involved a reaction that did not include ethylene glycol specifically?
MR. NIGH: Form objection.
A. Please repeat your question.
Q. You said that this talked about the reaction of sodium nitrite in ethylene glycol or an ethylene glycol equivalent. But I'm just asking you to confirm that all of the experiments described in these papers did use ethylene glycol, not some other equivalent?
MR. NIGH: Form objection.
A. I have not gone thoroughly through the paper. I can, if you wish me -- if you wish, I would go through the entire paper. However, you know, in chemistry, and in conducting root cause analysis, which is really what we're doing here, is we have a genotoxic impurity like tri -- like NDEA, and we're trying to figure out where it came from.
In the course of my investigation,

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looking at this trans -- chemical transformation, it -- the ethylene glycol can be, you know, potentially an alcohol. And we have plenty of that in the -- you know, in the -- in ZHP's transformation. There are esters that are present in the ZHP transformation.
And there are lots of other evidences from -- and statements from other investigators and other chemists, who have speculated that triethylamine converts to NDEA. So that's my assertion; that's my opinion. And I believe the source of NDEA is triethylamine.
Q. Okay. Again, I was not asking that question; I was really just asking about the use of ethylene glycol in this article. But I'll accept your answer that you, off the top of your head, don't know, and the article speaks for itself.
A. Yeah.
MS. ROSE: If we can look at page 357 of this document, as noted in the top right-hand corner. It's page 5 of the PDF.
Q. Can you see that on your paper?
MR. NIGH: Form objection to the colloquy before this.
MS. ROSE: It's Table 1. It's Table 1.

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I'm sorry, you're on Figure 3, I need to go to Table 1. Thank you.
Q. Are you there, Dr. Najafi?
Table 1 here is a chart entitled, "Ester-Mediated Nitrosation of Secondary Amines." Correct?
A. Yes.
Q. And dimethylamine, the secondary amine that you say is necessary to form NDMA in the zinc chloride proces, is not one of the secondary amines that were tested. Correct?
MR. NIGH: Form objection.
A. The answer is "correct." However, in -- when you are, again, trying to figure out the root cause, and do a root cause analysis of a genotoxic impurity, you rely on other transformations. Essentially, you say, if one plus one equals two, therefore -- and therefore, one plus two will be equals three. So, you know, you -- you know, it's very much translatable. It's very much in chemical reactions, it's -- you often rely. If trimethylamine converts to NDMA, triethylamine will convert to NDEA.
And tripropylamine, we may not have any evidence for tripropylamine. But because trimethylamine converts, therefore tripropyl will

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too. It's -- it is very well understood in chemistry for the last probably three, four hundred years.
Q. Okay. Dr. Najafi, when did you first personally become aware that dimethylamine, in the presence of sodium nitrite, could result in the formation of NDMA?
MR. NIGH: Form objection.
A. When did I personally -- your question again, when did I personally became aware that dimethylamine converts to NDMA?
Q. Yes.
A. I cannot recall. You know, I have been aware of nitrosamines since the late 1970s, and I have been engaged in the chemistry of nitrosamines. I had an interest in essentially avoiding sodium nitrite, in -- that are associated with curing the meat. So I have been aware of NDMA. I cannot recall exactly when I became aware of it, what year it was, and what time it was.
Q. Okay. But I wasn't asking when you become aware of NDMA, but when did you first become aware of the process by which dimethylamine, in the presence of sodium nitrite, that then converts to nitrous acid, that then converts to a nitrosonium ion, can result in the formation of NDMA? When did

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that reaction become known to you?
MR. NIGH: Form objection.
A. Probably 20-some years ago.
Q. And when did you first read this Loeppky article we've been discussing?
A. I have become aware of Loeppky article probably over the last 12 months, I would say, probably 12 months ago, maybe -- maybe more, as we were investigating presence of NDMA in various drug APIs.
Q. So you became aware of the Loeppky article after you were retained as an expert in litigation relating to valsartan?
MR. NIGH: Form objection.
A. That's correct.
Q. Okay.
MS. ROSE: I'd like to take a break for a couple of minutes. Where are we, 8:45? Remind me again -- we can go off the record. Remind me again.
THE VIDEOGRAPHER: Going off the video record, the time is 8:46.
(A brief recess takes place.)
THE VIDEOGRAPHER: We are back on the video record. The time is 9:03 a.m., and this begins Media Unit Number 2.

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MS. ROSE: I'm going to turn the questioning over now to counsel for Teva.
EXAMINATION BY MR. HARKINS:
Q. Good morning, Dr. Najafi. Can you hear me okay?
A. Good morning, Steven. Yes, I can hear you fine.
Q. Good. Well, I'm glad to say we got to meet already. And you understand that I'm counsel for the Teva defendants, one of the finished dose manufacturers in this case. Correct?
A. I understand.
Q. All right. And obviously, we'll just be proceeding with some questioning on that.
I understand that you also have a call in approximately 30 minutes that you're going to take a break for. Is that right?
A. That's correct.
Q. All right. Just let me know if that call comes in, and we'll figure out how to pause the questioning. Okay?
A. That will be great, thank you.
Q. All right. Dr. Najafi, my questions are going to be focused on the finished dose manufacturers in the case, who you understand are

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Teva and Torrent. Correct?
A. That's correct.
Q. And largely, I'm interested in finding out if you have an intent to offer opinions with regard to the finished dose manufacturers, and specifically, their conduct in this case. Okay?
A. Yes.
Q. You have a copy of your expert report with you; I believe it was previously introduced as Exhibit 7.
A. Correct.
Q. Can you take a look at page 11 of your expert report? Let me know when you have that available.
A. I have page 11 on the PDF.
Q. Please look at page 11 on the numbering in your report. So it will be small 11 at the bottom; I believe it's page 13 of the PDF.
A. That's exactly right, I have that.
Q. And take a look at the top paragraph of that section for me. And specifically, I'm interested in the sentence about halfway down that starts, "Finished dose manufacturers reference the DMFs."
Do you see that?

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A. I'm reading -- hang on a second. So I am -- yes, "finished dose" -- okay, I need to read the whole paragraph, Steven. Just give me a second.
Q. Are you finished?
A. Yes, I am.
Q. My question, Dr. Najafi, is: You are familiar with the process by which finished dose manufacturers reference a DMF in their ANDA. Correct?
A. Yes, I am.
Q. And that allows a finished dose manufacturer to incorporate API that's been manufactured by another company into their finished drug -- finished drug product. Correct?
A. That's correct.
Q. And that DMF may contain proprietary commercial processes that are not known to the finished drug manufacturer, but they are allowed to incorporate those by reference to the DMF. Correct?
A. That is correct.
Q. Dr. Najafi, last week during your testimony, you were asked if it was your opinion that as of 2013, finished dose manufacturers who looked at the TEA-with-quenching process should have known that it was going to result in the production of NDEA.

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And your answer to that question was: "Finished dose manufacturers, if they had access to the DMF, they should have -- you know, they should have been aware of the chemical process."

Do you recall that testimony?

MR. NIGH: Form objection.

A. I do.

Q. My question, Dr. Najafi: Have you reviewed documents to determine what information from ZHP's DMF on the process was available and known to the finished dose manufacturers, specifically Teva?

MR. NIGH: Form objection.

A. Steven, I do not know what documents Teva has reviewed as it relates to ZHP's Drug Master File. But, you know, there's no question that, you know, that the finished dose manufacturer is responsible for evaluating the API. If they have access to the chemical routes of synthesis, then obviously, they need to do risk analysis. If they don't have access to it, then they need to thoroughly test the API, and do what we -- what I call untargeted analysis, similar to what Novartis did.

And Novartis, in this case, is a finished dose manufacturer, just like Teva. And do their due diligence with the API, do an identity

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test; conduct a residual solvent analysis, which is prescribed by the various regulatory authorities; the USP, you know, FDA, EMA; everybody prescribes what they need to do, in order to make sure that their finished dose does not contain any of the Class 1 or genotoxic impurities or solvent impurities. And, you know, that would be, you know, the responsibility of your client.

In addition, they would need to have a quality agreement in place, and also conduct a thorough quality check inspection of the API manufacturer.

Q. Dr. Najafi, I'm not asking generally about what your opinion is, as to what the finished dose manufacturers should have done. I understand that from your report.

My question is: You have not analyzed or reviewed documents to determine what information on ZHP's chemical processes was actually available to the finished dose manufacturers when they submitted their ANDAs. Correct?

MR. NIGH: Form objection.

A. I do not know whether your client, Teva, has reviewed any material -- any -- what they reviewed, as it relates to ZHP's DMF.

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Q. Great.

Your opinion that a reasonable chemist from the finished dose manufacturers would have identified the potential for nitrosamines to form assumes that the finished dose manufacturers had access to chemical -- the information on ZHP's process. Correct?

MR. NIGH: Form objection.

A. If they had access to ZHP's process, then they could have conducted a root cause analysis. So the answer is yes.

Q. And if they did not have access to it, they would not have been able to conduct that analysis, naturally. Correct?

MR. NIGH: Form objection.

Q. And my question is just with regard to that analysis; not another analysis, just that analysis, that root cause analysis that you described. If they did not have access to it, then naturally, they wouldn't have been able to conduct it. Right?

MR. NIGH: Form objection.

A. So it's really not root cause analysis; it's really risk analysis. So if they had access to the routes of synthesis, the chemical -- the chemical

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synthesis, then they could conduct risk analysis of various reagents that are present.

And there must have been something in the ANDA that says the route of synthesis was changed, so they must have been aware that the synthetic route has been modified by ZHP, and they could have further investigated that.

So there is the -- there is the upfront risk analysis, and then there is the back-end analysis of the API that your clients should have conducted.

Q. Dr. Najafi, I'm talking just specifically with respect to the analysis that you testified an organic chemist would have been able to perform, with access to information about the process. If they did not have information about that process, they would not have been able to conduct any type of analysis, the analysis that you just described. Right?

MR. NIGH: Form objection.

A. If the chemists at Teva did not have access to routes of synthesis, then obviously they could not have conducted a risk analysis. However, there were indications that ZHP changed the process, and they have -- and, you know, and there was

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various, you know, information that -- in the DMF that the process was changed, you know, and various solvents were changed and so forth.

So there were some indication that things are not the same as the brand product.

Q. Dr. Najafi, there is no requirement that a finished dose manufacturer have access to the closed portion of another company's DMF in order to manufacture drug products under an ANDA that references that DMF. Correct?

MR. NIGH: Form objection.

A. Could you repeat your question?

Q. Sure. There is no requirement for a finished dose manufacturer to have access to the closed portion of another company's DMF, in order to manufacture drug products under an ANDA that references that DMF. Correct?

MR. NIGH: Form objection.

A. That is correct -- that is correct. However, as I mentioned, the drug substance manufacturer should have notified the finished dose manufacturer of the changes to the DMF.

Q. Understood.

I'd like to turn to another area of your report, Dr. Najafi. If you could go to page 36. And

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that is 36 on your report, which I'll confirm, I believe will be page 38 on the PDF.

A. Okay.

Q. Let me know when you're there.

A. Page 38 of the PDF.

Q. Do you see the heading "Qualification of a Drug Substance (API) Supplier by a Finished Dose Manufacturer"?

A. No, I don't. Hang on one second. I think you're on page 36 of the PDF. Okay, hang on.

Q. It's the section showing on the screen share. Again, it's definitely 36 on the small page on the bottom of your report. I believe it's page 38 of the PDF you're looking at.

A. Right. I'm looking at it. "Qualification of a Drug Substance (API) Supplier by a Finished Dose -- Finished Drug Product Manufacturer."

Q. And Dr. Najafi, I understand, and I think this paragraph covers a lot of what you talked about in response to one of my earlier questions, about what you believe are the obligations of a finished dose manufacturer as far as qualifying an API, validating a supplier, and having a quality agreement; I believe are all covered in this

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paragraph. Take a moment if you want to refresh on that.

MR. NIGH: Form objection.

A. Okay.

Q. Dr. Najafi, neither of the finished dose manufacturers, Teva or Torrent, are identified by name in this section of your report. Correct?

A. That's correct.

Q. And there are no citations, either in a footnote or in the body of the report, to any documents in this section of your report. Correct?

A. That's correct.

Q. I understand your opinions with respect to what a finished dose manufacturer should do in these areas, as you stated already today. Have you -- strike that.

Do you intend to offer opinions on the adequacy of the supplier qualification process performed by the specific finished dose manufacturers in this case with respect to ZHP? Have you formed those opinions?

MR. NIGH: Form objection.

A. Based on -- yes, I have. So based on the fact that they obviously incorporated the ZHP's API in their final drug and marketed it, it was

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obvious that they had not done comparable due diligence as Novartis, which is another finished dose manufacturer in this case.

And they basically must have relied on ZHP's certificate of analysis, and -- or they may not have done sufficient due diligence, you know, to qualify the API.

So that is an opinion that I've actually expressed in various parts of my report, and I'm expressing right now.

Q. Dr. Najafi, you did not review the actual supplier qualification documents from Teva and Torrent to form this opinion; you are assuming that this process was deficient because whatever they did, it did not identify the potential for nitrosamines to form during ZHP's manufacturing process. Is that fair?

MR. NIGH: Form objection.

A. That is correct. My opinion is primarily based on the fact that they allowed this genotoxic impurity in their finished product and they marketed it, and -- as opposed to Novartis, who ran a very simple GC-FID and saw a very -- very messy chromatogram, you know, in comparison to ZHP's own certificate of analysis, and they said, this doesn't

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jive and we need to do further investigation.
I think my opinion is that ZHP -- your client simply rushed and they took -- they took the risk. Essentially, they accepted the risk and they moved forward.
Q. And just to confirm: When you say "rushed" or "accepted the risk," that is based on what you are assuming, based on the fact they failed to identify the impurity; not your independent review of the supplier qualification documents for Teva. Right?
A. Yes.
Q. So a similar question, and I just want to make sure I understand where you do and don't have opinions. Did you evaluate the finished dose manufacturers' quality policies for adequacy?
MR. NIGH: Form objection.
A. I don't believe so.
Q. Did you evaluate and form opinions on the adequacy of the finished dose manufacturers' quality management systems?
A. I don't believe I had access to those documents.
Q. And then at the end of your paragraph, you refer to quality agreements. Did you review the

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finished dose manufacturers' quality agreements with ZHP, and form opinions on the adequacy of those agreements?
A. I don't believe that the quality agreements were provided to me. But again, I'm simply looking at the final, you know, act, which is incorporating this, you know, sort of adulterated API in their finished -- you know, finished product. And, you know, the outcome is, obviously, they didn't do sufficient due diligence.
Q. I understand, Dr. Najafi.
And then the final thing I just want to confirm: You have a reference in here, about two-thirds of the way down the paragraph, to: "In addition to the documentation, the qualification process should include testing of API batches."
Do you see that?
A. Would you highlight that? And -- okay.
Yes.
Q. Did you review and evaluate any of the chromatography testing results for the API that Teva performed?
A. I don't believe I have.
Q. And generally speaking, just for those areas where you did not review documents, is it fair

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to say you have not formed opinions that you intend to offer on the adequacy of those specific areas?
MR. NIGH: Form objection.
A. While I have not reviewed any chromatography testing that Teva or Torrent might have done, the end result is, even if they had done it, they did not do sufficient due diligence. And they might not have done it.
Q. But you -- just to clarify, you've not reviewed documents to know, one way or another, whether they did it, or whether the specific testing was appropriate or accurate. Correct?
MR. NIGH: Form objection.
A. I think -- I think I already answered the question.
Q. You may have. Is the answer yes?
MR. NIGH: Objection to form.
A. As I said, I have not seen any chromatograms from Teva and Torrent, so -- I don't believe I have seen anything. However, based on the fact that their finished dose -- their finished product contained the NDMA and they allowed it, so it's obvious that they didn't do sufficient due diligence and sufficient analysis of the API.
Q. And Dr. Najafi, I understand your

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opinion with respect to the due diligence. I'm asking specifically with regards to the chromatography testing.
And I want to just confirm: You have not reviewed any of the results of the finished dose manufacturers' chromatography testing to determine if the testing itself -- unrelated to supplier qualification -- if the testing itself was appropriate or accurate, have you?
MR. NIGH: Objection, asked and answered multiple times.
A. They were not provided to me, but I'm happy to review them if you have them in front of you.
Q. No need, Dr. Najafi.
And I think -- let me see -- one question, I guess, before we may go on our break here. You have not seen any evidence that Teva was aware of the potential for nitrosamine formation in valsartan API or valsartan drug products prior to June 2018, have you?
MR. NIGH: Form objection.
A. I don't believe I have seen anything pointing to Teva knowing that there's NDMA in the valsartan API. However -- however -- so I answered

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your question. However, the quality -- the QA inspection by Teva, and the quality agreement, should have pointed to potential complaints regarding impurities pre-2018. And those -- those should have raised their -- sort of doubt about the quality of API.

MR. HARKINS: Thank you, Dr. Najafi.

Can we go off the record for a moment?

THE VIDEOGRAPHER: Yes.

We're going off the video record. The time is 9:29 a.m.

(A brief recess takes place.)

THE VIDEOGRAPHER: We are back on the video record. The time is 9:51 a.m. This begins Media Unit Number 3.

BY MR. HARKINS:

Q. Dr. Najafi, during the first day of your deposition last week, you were asked when Emery Pharma's next FDA inspection was going to be scheduled for. And you answered, "It could be today, nobody knows. It's a surprise audit."

Do you recall that testimony?

MR. NIGH: Form objection.

A. Yes, I do.

Q. You aren't always able to prepare for a

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FDA audit in advance. Correct?

MR. NIGH: Form objection.

A. You know, are you asking me on the -- on the Emery side, or on the -- say, a manufacturer?

Q. In your experience working at Emery Pharma, as you testified, it could be a surprise audit. Is it your experience that FDA does not always schedule its audits in advance?

MR. NIGH: Form objection.

A. They do not always schedule their audits in advance.

Q. And when they perform an audit, do they always inform you what products or systems are going to be subject to the audit in advance?

MR. NIGH: Form objection.

A. I can only -- only speak from my experience. And no, they may just come and do a -- want to do a general audit. They may point to a specific product that they want to focus on. So it's really entirely up to them.

Q. Switching gears a little bit.

You're familiar, during your review for this case, with the unidentified impurity standards that are contained in the approved ANDAs for the finished dose manufacturers, aren't you?

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A. Do you have anything you want to show me, like a, you know, impurity profile, chromatogram? What are you pointing at? Are you pointing at API identity impurities, as it relates to API? Or are you pointing to impurities as it relates to residual solvents?

Q. I'm referring to impurities, not with respect to residual solvents; the impurity standards with regard to the API. Does that help clarify the question?

MR. NIGH: Form objection.

A. I think you're referring to -- impurities as it relates to API, you're referring to USP-related impurities.

Q. Have you reviewed the unidentified impurity standards set out in the ANDAs for the finished dose product in this case?

MR. NIGH: Form objection.

A. I might have.

Q. But you're not familiar with them, off the top of your head, without seeing a document?

MR. NIGH: Form objection.

A. You know, you need to show me a document.

Q. Dr. Najafi, what's a reporting

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threshold?

MR. NIGH: Form objection.

A. A reporting threshold, as it relates to any impurities, essentially non-genotoxic impurities, is around 0.1, 0.1 percent. However, for genotoxic impurities, there are no reporting thresholds.

Q. And Dr. Najafi, my question may have been confusing. I'm not asking what the specific reporting threshold is. I'm asking, what is a reporting threshold? What does that delineate as far as what a manufacturer is required to do if they see a result above or below that threshold?

MR. NIGH: Form objection.

A. Do you have anything you want to show me, point to me?

Q. Are you not familiar with how a reporting threshold operates, with respect to drug substances?

MR. NIGH: Form objection.

A. You have to define to me what that means.

Q. Assuming that a reporting threshold for a given drug substance is .05, I'll ask you to assume that for purposes of this question. Assuming that --

(Simultaneous speaking.)

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(Court Stenographer clarification.)
Q. And I apologize; this may be a long question, but just let me finish it for you, Dr. Najafi.
Assuming that a reporting threshold for a drug substance is set at 0.05 for purposes of this question, what does that require the drug substance or finished dose manufacturer testing that drug substance to do with respect to unidentified impurities?
MR. NIGH: Form objection.
A. I'm assuming you're talking -- when you say 0.05, you're talking about 0.05 percent?
Q. Yes, you're -- yes, Doctor, that's correct. Apologies.
A. So assuming their reporting threshold is 0.05 percent, if they see impurities that fall below 0.05 percent, batch after batch, they have the duty to investigate it. And in this case, not call an impurity -- it could be 0.0001 percent. If they can see it, and it shows, baseline to baseline, there is an impurity, they need to identify it. They need to point to it, and, you know, figure out what it is.
Because it could be a genotoxic agent. And if it is a genotoxic agent, then they need to

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control it, they need to figure out why it's being generated, you know. And if it's a very high-level genotoxin, you know, then they need to obviously, you know, dispose of those batches, and, you know, do whatever they need to do: Report it to the agency.
So that's what, you know, a manufacturer, whether it's -- you know, the API manufacturer or finished dose manufacturer, that's what they need to do. And that's what exactly Novartis did. So we're not creating some hypothetical situation here. Novartis is a finished dose manufacturer, just like ZHP -- just like Teva and Torrent. And Novartis did the right thing and pointed those impurities -- and pointed at those impurities, and wanted to figure out what they are.
Q. But Dr. Najafi, I just want to make sure that I understand your opinion before we move on.
It's your expert opinion in this case that a finished dose manufacturer, observing a level of unidentified impurity below the reporting threshold, is required not only to report, but also to identify the substance that is causing that peak, regardless of size?
MR. NIGH: Form objection, mischaracterizes his testimony.

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You can answer.
A. So if a finished dose manufacturer or API manufacturer sees an impurity that is below the reporting threshold, 0.05 percent, let's assume, and they see this impurity repeatedly, and it is, obviously, a recent impurity in there, they should -- they don't have to -- they may not have to report it, but they must investigate it.
And if it is -- let's say, if it's a harmless solvent, and it's, you know, it's not -- they don't need to report it. But if it's a genotoxin, then they must report it, and they must control it, and, you know, put some guardrail around that impurity.
Q. And Dr. Najafi, just to confirm from your testimony before the break: You did not review the results of the chromatograms performed by either of the finished dose manufacturers to determine what, if any, levels of unidentified impurities they were seeing in ZHP's API. Correct?
MR. NIGH: Form objection, asked and answered.
A. As I mentioned before, I did not review ZHP [sic] and Torrent's chromatogram. But if you have it in your -- in front of you, please feel free

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to share it with me, and I'll be happy to give you my opinion.
Q. Dr. Najafi, I'd like to turn to page 6 of your report to help you with this next question. That's going to be -- I apologize, I may have gotten the number wrong. Page 6, and it will be page 8 of the PDF. Let me know when you're there.
A. Six, yes.
Q. And looking at the bottom paragraph on page 6, you reference "a single 320-milligram valsartan tablet."
That's the highest daily dose you've identified for any valsartan tablet involved in this case. Correct?
A. Please allow me to read the paragraph quickly.
Yes, I read it.
Q. And just to confirm -- hopefully, it would help to read your report -- 320 milligrams is the highest daily dose of valsartan that you're aware of. Correct?
A. Correct.
Q. Go to the next page of your report, seven.
A. Okay.

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Q. And I'm suspecting you're going to want to read through these paragraphs that finish this section.

My question is going to be: Is the 240.1 PPM number, identified in the second full paragraph on this page, the highest level of NDMA that you have identified reported in valsartan API?

A. Let me -- let me review the -- okay.

So what is your question?

Q. Based on the paragraph that you just reviewed, is 240.1 parts per million the highest level of reported NDMA impurities present in valsartan API that you're aware of?

A. This is in the previous paragraph?

MR. NIGH: Form objection.

Q. Sorry, the continued section, that starts at the top of page 7 --

A. Right.

Q. There's a broken paragraph, and then two full paragraphs.

A. Right. Okay.

Q. The bottom of the second paragraph --

A. Point-two --

Q. Right.

A. Could you point to that number of

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milligram pills that you're talking about?

(Simultaneous speaking.)

(Court Reporter Clarification.)

Q. The reference that you wrote about the milligrams of pills is on the prior page. But in the next page of your report, at the bottom of this section, in the paragraph that begins, "ZHP also manufactured," there are references to reported levels of impurities in parts per million.

A. Correct.

Q. And one that is 240.1.

And my question is: Are you aware of any higher level of NDMA or NDEA impurities reported in any valsartan API?

A. 240 -- yeah, 240 -- you know, there might be, that's what I was shown, that's what the document is pointed -- I pointed to.

(Cell phone ringing.)

A. Let me turn off my phone; I'm sorry.

Q. Just to confirm --

A. Yeah.

Q. You are not aware, based on documents that you have reviewed, of any higher level reported in valsartan API. Correct?

A. I am not aware, but there may be other,

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you know, pills with more parts per million.

Q. Dr. Najafi, for purposes of this question, I'm going to ask you to assume that the reporting threshold for valsartan API is 0.05 percent. 240.1 parts per million would be less than half of that reporting threshold on a chromatogram. Correct?

MR. NIGH: Form objection.

A. I take your word for it.

Q. Dr. Najafi, I'm not asking you to take my word for it. I do ask you to assume the reporting threshold for purposes of this question. But assuming that that is the reporting threshold, at 0.05 percent, is it accurate that 240.1 parts per million of an NDMA impurity in the valsartan API would be less than half of that reporting threshold?

MR. NIGH: Form objection, vague.

A. Okay.

(Court Stenographer clarification.)

MR. HARKINS: Did you hear that? Can you just say your answer again, Dr. Najafi, for the court reporter.

A. Yes.

Q. Dr. Najafi --

MR. HARKINS: And you can take the

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report down for a moment.

Q. During questioning last week, you discussed how Emery Pharma assists manufacturers with testing. Do you recall that, generally?

A. Yes, I do.

Q. And one of the things that you said, when releasing product or assisting with releasing product, is that you provide your clients with a certificate of analysis. Is that correct?

A. That's correct.

Q. The certificate of analysis contains information on tests that were performed on either that drug substance or a drug product. Right?

A. That's correct.

Q. Are those the tests that are required by the approved specifications for that drug substance or drug product?

A. What tests are you referring to?

Q. That's kind of my question. Do you do limited testing, as requested by the client? Or do you perform complete testing of a drug substance or a drug product, such that they could release the product without further testing? That's really my question.

MR. NIGH: Form objection.

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A. It depends on the product. It depends on what the client is asking us to do. In this case, if we were to -- given an API and say, do -- take a look at the -- here is the certificate of analysis from the manufacturer, let's say, ZHP; and typically, it should contain seven solvents, and do residual solvent analysis.

And if they do a residual solvent analysis, and if they're supposed to have seven solvents, and we see 20 different peaks, I think we immediately contact the client and say, we're seeing far too many peaks here.

Which is really what Novartis saw. And we communicate that to the client and say, "What do you want us to do? You know, we need to investigate these other peaks."

In this case, you know, 240 parts per million, this translates into -- one nanogram per milligram translates into one parts per million. Right? One nanogram per milligram; that's one part per million. Now, if you are --

Q. Given that I have very limited time -- I almost never want to interrupt, but this is not remotely responsive.

MR. NIGH: Let's go ahead. Let's go

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ahead. I think it's been answered, too. You can ask the next question.

MR. HARKINS: Okay.

Q. Dr. Najafi, if my question is confusing or you're unsure what I'm asking, let me know, so I can kind of try and keep us on track.

All I'm asking is: Does Emery Pharma sometimes do all of the tests required by a certificate of analysis for release of a finished drug substance -- or for release of a drug substance?

MR. NIGH: Form objection.

A. We always do what is necessary to release a drug substance. In this case, if we had been tasked for releasing ZHP, we would not have released it.

Q. Understood.

When you provide your clients with the results of testing, do you provide them with the certificate of analysis, or do you also provide them with all of the raw chromatography and other testing data that supports the results in the certificate?

MR. NIGH: Form objection.

A. It depends. Often we provide them with a report, a full report with chromatograms; be it, you know, what are some of the prescribed testing.

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We often have some chromatograms associated with them. We provide them with all that documentation, plus a certificate of analysis.

Q. Okay. And I understand that you sometimes do that. Do you sometimes also just provide them with a certificate of analysis?

A. Almost always not.

Q. We discussed, during your testimony last week, the April 2021 483 that Emery Pharma received. Do you recall that?

A. Yes, I do.

Q. Do you recall that discussion?

A. Yes, I do.

Q. And I understand from your testimony that, at some point after receiving that, the issues identified in that 483 were addressed by Emery Pharma. Correct?

MR. NIGH: Form objection.

A. That's correct.

Q. Was Emery Pharma continuing to perform testing and assisting with the release of product for its customers in April of 2021?

MR. NIGH: Form objection.

A. Yes, we continued testing and releasing product, post inspection.

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Q. And then you continued to do that, while you were working to correct the issues identified in the 483. Correct?

MR. NIGH: Form objection.

A. I think I mentioned that in my testimony, that the FDA allowed us to continue our release or testing, because they found no issues with our testing protocols and the chemistry of the work we did.

Q. And you did not consider any of the product released by Emery Pharma, during the time that the issues identified in that 483 were present, to be adulterated?

MR. NIGH: Form objection.

A. That's correct.

Q. And you didn't take any steps to remove any of that product released, based on testing performed by Emery Pharma, during that time from the market?

MR. NIGH: Form objection.

A. That's correct, because the 483 was not related to the actual testing.

Q. Understood. And you didn't take any steps to inform patients or physicians about any concerns about product quality, for product that was

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released during the time that those issues were present and being corrected. Correct?
MR. NIGH: Form objection.
A. That's correct, because the 483 was not related to testing. However, we did inform the -- many of our clients that we had this 483.
Q. And just to confirm: When you're saying "clients," you mean the manufacturers, not patients and physicians and things like that. Right?
A. That's correct.
Q. But you testified just a little bit ago that you perform required testing on products that you're releasing to the market, which may or may not be all of the tests required in the certificate of analysis. Is that fair?
A. Could you repeat your question?
Q. Sure. That was a poor question. Let me strike that and just move on.
A. I think it was a statement.
Q. A lot of times, they sound like that.
Dr. Najafi, does Emery Pharma have GC-MS?
A. Yes, we do.
Q. Do you test all the products released by Emery Pharma using GC-MS?

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MR. NIGH: Form objection.
A. It depends on the product, and depends on the specifications associated with the product.
Q. And when you say "specifications," you're referring to the monograph USP specifications?
MR. NIGH: Form objection.
A. It might be the monograph from -- monograph from the USP; it might be the client's monograph. It all depends.
Q. Are you familiar, generally, with USP monographs and where they can be accessed?
A. We are a subscriber to USP, so we have access to it, yes.
Q. And as you said, the monographs set out certain testing to be performed on drug substances and drug products. Is that fair?
A. That's correct. However -- can I continue?
Q. You can continue if you need, yes.
A. Yes. However, USP monogram -- monograph sets the minimum standard, and it's often related to the brand, you know, that was -- that had patents on. Once that USP -- once the product is modified, procedures are changed, the manufacturing is changed; pretty much all the impurity related to that

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monograph is out the window.
Q. Understood.
Dr. Najafi, are you familiar with how many USP-approved monographs there are?
A. No, I'm not.
Q. I'll represent to you, for purposes of this next question, that as stated in the expert report of plaintiffs' retained expert, Dr. Laura Plunkett, there are over 5,000. Okay? And that's just an assumption for the purposes of this next question. All right?
Assuming she is correct and there are over 5,000 monographs, are you aware of how many of those require the use of GC-MS testing to perform a specific assay?
A. I'm not sure.
Q. Coming back to the testing performed at Emery Pharma, when you perform release testing on product -- well, strike that.
Let me start with a question before that.
Dr. Najafi, what is structural characterization?
A. Structural characterization, it refers to what the molecular structure looks like.

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Q. In the context of an unidentified impurity that shows up on a chromatogram, what is structural characterization?
A. It means identifying what that impurity is. And characterizing it from often multiple different angle: Characterizing it by mass, characterizing it by checking against reference standards, potentially characterizing it by NMR, separating it. So there's a whole list of things that we conduct if we're tasked for characterizing an impurity.
Q. And structural characterization of an unidentified impurity would then enable you to determine what specifically that impurity is. Right?
A. Exactly.
Q. Does Emery Pharma include structural characterization of every impurity -- of every -- strike that.
Does Emery Pharma perform structural characterization of every unidentified impurity on chromatograms for products that it releases?
MR. NIGH: Form objection.
A. We're not a pharmaceutical company, and we're not a manufacturer. We do what the clients ask us to do, and we follow prospectively their

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prescribed procedure or monograph.
However, if we see -- you know, we have clients that come to us repeatedly with the same product that we need to release. We may release it once. And then next time we release it, if we see the same impurity, same place, same location, our internal team often brings that up and say, "This impurity is showing up over and over again." And we often alert the client that we need to -- we should -- we recommend they identify it. And identification of impurities, especially in --
Q. Dr. Najafi, I have very limited time with you --
A. -- is very easy.
(Court Reporter Clarification.)
Q. Dr. Najafi -- and I appreciate, and I understand your general comments there. My question is a little more specific.
Emery Pharma does not perform structural characterization of every unidentified impurity that shows up on the chromatogram in release testing that it performs for its clients. Correct?
MR. NIGH: Form objection.
A. We do what the clients ask us to do. You know, if Novartis comes to us and say, "We saw

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this chromatogram. We're trying to identify what are all these impurities," we do it for them. But we typically do what the clients want us to do.
Q. So unless a client asks you to perform structural characterization of every unidentified impurity for a given product, you would not undertake structural characterization of every unidentified impurity in products tested and released by Emery Pharma. Correct?
MR. NIGH: Form objection.
A. Yes, we are not a manufacturer. We're not responsible for their product. They are responsible for their product.
Q. Understood.
Dr. Najafi, are there unidentified impurities that you do not perform structural characterization on, that are present in product that is released, based on testing performed by Emery Pharma?
MR. NIGH: Form objection.
A. Yes, there are unidentified peaks that we often do not identify. However, if the client asks us to identify them, we identify them.
Q. And just to make sure that I'm clear on this. When you do structural characterization of an

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unidentified impurity, you're not discovering a new chemical compound, typically. Right?
MR. NIGH: Form objection.
A. What do you mean by a "new chemical compound"?
Q. Sure. When you perform structural characterization to determine that something is NDMA, that is not to say that NDMA was previously unknown to science; it's that it was unknown to be -- or unidentified as present in this particular substance. Is that accurate?
MR. NIGH: Form objection.
A. You know, there are really -- there's no new discoveries to be made. However, it could be. You know, sometimes the unidentified impurity is completely a novel compound, never been reported. Sometimes. Most often, what we discover as an unknown impurity you could actually, you know, look into the literature and see, you know, what -- who else has reported this impurity.
Q. I think I understand your answer.
You mentioned that ICH Q3A and Q3B contain guidance on the identification of unidentified impurities in both drug substances and drug products. Is that fair?

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A. I think Q3A points to genotoxins, and -- you know, identifying them. And, you know, Q3A is concerned for genotoxic impurities, as it relates to presence of genotoxic impurities in residual solvent analysis and so forth.
Q. And I want to be clear. Is it your understanding that ICH Q3A and B make specific recommendations for genotoxic substances?
MR. NIGH: Form objection.
A. Yes, they do.
Q. Okay.
MR. HARKINS: And if I could ask for some assistance introducing one of the exhibits that I've placed in the private share folder. It's the ICH Q3A guidance, which I believe will be marked as Exhibit 18.
(Exhibit Najafi-18, FDA Document entitled "Guidance for Industry, Q3A Impurities in New Drug Substances," Revision 2 dated June 2008, No Bates, 17 Pages, was received and marked for identification.)
Q. Dr. Najafi, now, I'd like you to be able to review this. It should be included in the Dropbox as well, to the extent you need to.
Are you familiar with this Q3A,

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"Guidance For Industry, Impurities in New Drug Substances"?
A. Yes, I am. I don't -- I don't have this guidance in the -- in the Drop -- in the -- in the share folder.
THE VIDEOGRAPHER: It should be there if you refresh the page.
A. Okay, got it. Yes.
Q. All right. Dr. Najafi, do you now have access to the document?
A. Yes, I do.
Q. I'd like you to turn to page 10 of the guidance.
A. Okay.
THE VIDEOGRAPHER: Is that PDF page 10 or document page 10?
MR. HARKINS: It will be page 10 of the guidance itself. It's page 13, I believe, of the PDF.
Q. All right. Dr. Najafi, you see here how ICH Q3A defines an unidentified impurity? Do you see that definition, the second from the bottom?
A. Ten? Okay.
Q. Are you there?
A. Second from the bottom. "Unidentified

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impurity," [inaudible]. Yep.
Q. And --
A. I see it.
Q. And you see the definition here: "An impurity for which a structural characterization has not been achieved, and that is defined solely by qualitative analytical properties (e.g. chromatographic retention time)."
Is that correct?
A. That's correct.
Q. You are not aware of any structural characterization of NDMA in valsartan drug substance, prior to June of 2018, are you?
MR. NIGH: Form objection.
A. NDMA has been around since the late '70s, and it is a volatile impurity.
Q. Dr. Najafi, my question is about the impurity in API, valsartan API, not any other context; and whether you're aware that it has been structurally characterized in valsartan API?
A. I will -- I will attest to you that in chromatograms of the API, NDMA will be invisible. It will be there, but it will be invisible. Because it has no UV activity. Almost all chromatography is done with a UV detector. And NDMA is there, but it's

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undetected.
Q. Understood, and I do appreciate that clarification.
Dr. Najafi, my question is: Are you aware of any structural characterization of NDMA or NDEA impurities in valsartan API that occurred prior to June 2018?
MR. NIGH: Form objection.
A. Not in valsartan in particular, but I think there were hints of nitrosation of valsartan by Dr. Lee, in -- prior to June of 2018, and there is plenty of evidence that NDMA is just created from sodium nitrite.
Q. And I understand that's your opinion, Doctor, I think it's well-established, and I'm not trying to dispute that. I'm just asking to confirm that hints of nitrosation or those other things you're referring to, those are not structural characterization of the impurity. Correct?
MR. NIGH: Form objection.
A. I believe it's structural characterization. There were some structural characterization of nitrosated valsartan, or maybe it was losartan, or the other sartans. I'd have to refer back to that testimony.

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Q. And I'm sorry, so now you're saying you do believe that someone performed a structural characterization of NDMA or NDEA in valsartan, prior to June 2018?
A. There were hints of characterized impurities of -- nitrosated impurities of a sartan. And that's -- it was actually from a testimony of Dr. Lee.
Q. Dr. Najafi, I want to be real clear.
I believe I understand what you just described as the steps that you would take to perform a structural characterization. Are you aware of those steps being taken by anybody with respect to valsartan drug substance, prior to June 2018?
MR. NIGH: Object to form; it's been asked and answered.
A. As I mentioned to you before, the only thing that I'm aware of is Dr. Lee's testimony, which you can actually bring it up. And there is a reference to ZHP doing some analysis of a -- they were aware that there is a nitrosation happening, because they saw nitrosation of a sartan. It doesn't have to be valsartan; it could be other sartans.
Q. Dr. Najafi, are you aware of any information that was known to Teva or the other

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finished dose manufacturer, Torrent, on the structural characterization of any nitrosamine impurities in valsartan drug substance prior to June 2018?

A. They might have been aware, I don't know. I have -- I have not been provided any documents that points to the fact that they were aware.

Q. Doctor, if you can go ahead and turn to the next page of the Q3A guidance. At the top, it indicates "Attachment 1, Thresholds."

A. What page are you talking about?

Q. It's the very next page: Number 11 on the document, number 14 in the PDF.

A. Okay.

Q. Let me know when you're there.

A. Yes, I'm here.

Q. The first column here indicates "Maximum Daily Dose." You would agree that the 320-milligram valsartan pill would fall under the first row: Less than or equal to two grams per day. Correct?

A. That's correct.

Q. And the reporting threshold, which is indicated here, is that 0.05 percent that we previously discussed and, as we previously discussed,

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that reporting threshold would be more than double the maximum reported amount of nitrosamine in ZHP valsartan API that you are aware of. Correct?

A. Correct.

Q. And the Identification Threshold, which is the next column, has a value of 0.10 percent. Correct?

A. That's correct.

Q. But that identification threshold would be more than four times higher than the 240.1 parts per million, which is the highest level of reported NDMA in any valsartan API of which you are aware. Correct?

A. That's correct.

Q. Dr. Najafi, I'd like to turn to the -- page 13 of the document. And this is page 16 in the PDF. This contains, under Attachment 3, a graph for "Decision Tree For Identification and Qualification." Do you see that?

A. That's correct.

Q. Now, this does not provide any instructions as far as the reporting threshold, which was that smaller threshold. Let me know if you disagree; I don't see it on here.

A. That's correct.

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Q. And according to the ICHQ3 guidance, if the impurity is greater than the identification threshold, which is 0.01, there are certain actions that are taken, including identifying the structure.

Do you see that first step?

A. Could you repeat your question, please? Sorry about that.

Q. Sure. The starting point for this decision tree is to determine, "Is the impurity greater than the identification threshold?"

You see that. Correct?

A. Right, exactly.

Q. And maybe this will short-circuit it.

If the impurity is not greater than the identification threshold, the ICH guidance Q3A indicates that no action should be taken. Is that correct?

A. Correct.

MR. HARKINS: Let's go ahead and take that down. I'd like to introduce the next exhibit. It's going to be ICH Q3B.

(Exhibit Najafi-19, FDA Document entitled "Guidance for Industry, Q3B(R2) Impurities in New Drug Products," Revision 3, August 2006, No Bates, 18 Pages, was received and marked for

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identification.)

(Court Stenographer clarification.)

(A discussion is held off the record.)

THE VIDEOGRAPHER: Going off the video record. The time is 10:40 am.

(A brief recess takes place.)

THE VIDEOGRAPHER: We're back on the video record; the time is 10:50 a.m.

MR. HARKINS: Thank you, Dr. Najafi, those are all the questions I have for you. I'm going to turn it over for counsel for Torrent, who may have some additional questions.

EXAMINATION BY MS. NAGLE:

Q. Hi, Dr. Najafi. How are you? My name is Brittney Nagle, and I --

A. I'm good, thank you.

Q. I represent the Torrent defendants. And I have just a handful of quick clarifying questions that relate back to some of your testimony earlier, that you gave when you were being questioned by Mr. Harkins.

Dr. Najafi, did you review any Torrent documents to determine what information was available to Torrent from the ZHP DMF?

A. I might have reviewed some documents,

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but are you -- do you have a specific question?
Q. So my question -- you testified earlier that you were not -- you were not aware of what documents Teva reviewed, as it related to ZHP's DMF; and I want to know if the same is true of Torrent?
A. I've only reviewed what was provided to me through the lawyers, so.
Q. Okay. Also earlier during your testimony, you confirmed for Mr. Harkins that when you say the finished dose manufacturers "rushed and accepted the risk," that was based on your assumption that they must have rushed because they didn't identify the impurity, and not based on an independent review of documents from Teva.
Do you remember that?
MR. NIGH: Form objection.
A. It is my conclusion that -- based on the fact that they allowed the genotoxic impurity to be released in the drug product.
And Novartis just did a temp hold GC-FID, GC-F -- GC-FID. And by GC-FID, they were able to see a lot of impurities, and they didn't want to take that chance. They could have -- they could have gone ahead too, but they didn't.
Q. Okay. So just to be clear, that's

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not -- that opinion is not based on documents you reviewed from Torrent. Correct?
A. I have reviewed a lot of documents. I do not recall specifically, you know, any chromatogram. But if you have anything you want to share with me, I'll be happy to review, give you my opinion.
Q. Okay. So that leads to my next question, which is: Did you review and evaluate any of the chromatography testing for API that Torrent performed?
MR. NIGH: Form objection.
A. I do not recall.
Q. Okay. And Dr. Najafi, have you seen any evidence that Torrent was aware of the potential nitrosamine formation in the API or valsartan products prior to June 2018?
A. I cannot know if they were aware. You know, I've reviewed a lot of documents, but I am not aware of documents specifically pointing to the fact that they were aware.
Q. Okay. That was all --
A. From the documents that I've reviewed, based on the documents that I reviewed.
MS. NAGLE: Okay. That was the last

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question I have for you, Dr. Najafi, thank you.
MR. NIGH: Okay. Let's go ahead and take a break and go into the breakout room.
THE VIDEOGRAPHER: Going off the video record. The time is 10:54 a.m.
(A brief recess takes place.)
THE VIDEOGRAPHER: We are back on the video record. The time is 11:05 a.m.
MR. NIGH: Okay. It's my understanding that Torrent, Teva and ZHP have finished their questioning. There's nobody else on the defense side, right?
MR. HARKINS: Correct.
MS. ROSE: Yep.
MR. NIGH: Okay. At this time, we don't have any other questions; we're done. Thank you.
THE VIDEOGRAPHER: Going off the video record; the time is 11:05 a.m.
(The proceedings concluded at 11:05 a.m. Pacific Time)

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DANIEL NIGH, ESQ.
dnigh@levinlaw.com
January 27, 2023
RE: In Re: Valsartan, Losartan, Et Al
1/24/2023, Ramin (Ron) Najafi , PhD (#5677117)
The above-referenced transcript is available for review.
Within the applicable timeframe, the witness should read the testimony to verify its accuracy. If there are any changes, the witness should note those with the reason, on the attached Errata Sheet.
The witness should sign the Acknowledgment of Deponent and Errata and return to the deposing attorney. Copies should be sent to all counsel, and to Veritext at cs-nj@veritext.com.
Return completed errata within 30 days from receipt of testimony.
If the witness fails to do so within the time allotted, the transcript may be used as if signed.
Yours,
Veritext Legal Solutions

JURAT.

I DO HEREBY CERTIFY that I have read the foregoing transcript of my deposition testimony and I certify that is it true and correct to the best of my knowledge.

SWORN AND SUBSCRIBED
BEFORE ME ON THIS
DAY OF 2023

Notary Public of the State of

ATTACH TO DEPOSITION OF RAMIN (RON) NAJAFI, Ph.D.:
IN THE MATTER OF: VALSARTAN

DATE TAKEN: January 24, 2023

ERRATA SHEET

INSTRUCTIONS: After reading the transcript of testimony, please note any change, addition or deletion on this sheet. DO NOT make any marks or notations on the transcript itself.

Please sign and date this errata sheet and return it to the court reporter whose name is shown below.

PAGE LINE CHANGE

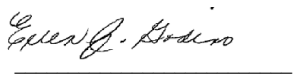
DATE and SIGNATURE:

CERTIFICATE

I, ELLEN J. GODINO, CCR, CRCR, RPR, do hereby certify that prior to the commencement of the examination, DR. RAMIN (RON) NAJAFI was duly sworn by me to testify the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.



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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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